National Digestive Diseases Information Clearinghouse

NDDIC News

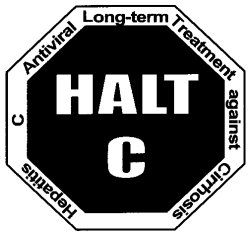
WINTER 2000–2001

NIDDK Sponsors Largest Hepatitis C Study

To try to prevent the development of cirrhosis and liver cancer in people with chronic hepatitis C, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is funding a clinical trial of long-term antiviral treatment using the drugs interferon (in a new form) and ribavirin. The trial, called HALT-C (Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis), will be conducted at 10 Hepatitis C Cooperative Research Centers across the country. Spanning 8 years and involving more than 1,300 patients, HALT-C will be the largest and longest hepatitis C study ever conducted.

Hepatitis C affects almost 4 million Americans, or 1.8 percent of the U.S. population. The virus causes an estimated 8,000 to 10,000 deaths annually in the United States and accounts for 60 to 70 percent of chronic hepatitis cases, and 30 percent of cirrhosis, end-stage liver disease, and liver cancer cases. At least 75 percent of patients with acute hepatitis C ultimately develop chronic infection, and most of them have accompanying chronic liver disease. Liver failure from hepatitis C is the most common reason for a liver transplant.

More than half of all patients treated with interferon and ribavirin do not respond. If the virus is still present after 6 months of treatment, therapy is usually discontinued. In the HALT-C trial, researchers want to learn whether continuing treatment beyond this point will decrease liver damage in the long run.



Researchers will recruit 1,350 people with chronic hepatitis C who have been treated unsuccessfully with interferon (with or without ribavirin). These participants will receive pegylated interferon

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Health Disparities Discussed at NDDIC Coordinating Panel Meeting

At the National Digestive Diseases Information Clearinghouse's (NDDIC's) annual Coordinating Panel meeting in June, participants heard from guest speaker Bruce Trotman, M.D., about gastrointestinal health disparities among minorities. Dr. Trotman is the chair of the American Gastroenterological Association's (AGA's) Underrepresented Minorities Committee.

PANEL MEETING, *continued on page 2*

NIDDK

National Institute of Diabetes and Digestive and Kidney Diseases
NATIONAL INSTITUTES OF HEALTH

What's New From NDDIC?

The National Digestive Diseases Information Clearinghouse (NDDIC) is pleased to announce several new and updated publications. All NDDIC materials are available at *www.niddk.nih.gov* on the Internet. Print versions are available through the clearinghouse using the publications order form insert.

New

- *Hemochromatosis.* This fact sheet discusses the causes, symptoms, diagnosis, and treatment of hereditary hemochromatosis, one of the most common genetic diseases in the United States.
- *Liver Biopsy.* This fact sheet describes liver biopsy and tells patients what they can expect before and after this diagnostic procedure. *Liver Biopsy* is the latest addition to *Diagnostic Tests,* a series that describes various diagnostic tests for digestive diseases.

Updated

In the past year, NDDIC updated several publications to include new information:

Fact Sheets

- *Chronic Hepatitis C: Current Disease Management*
- *Cirrhosis of the Liver*

Information Packets

- *Anal Fissure*
- *Autoimmune Hepatitis*
- *Diagnostic Tests for Liver Disease*
- *Fecal Incontinence*
- *Gallbladder and Biliary Tract Diseases*
- *Gastroesophageal Reflux Disease in Children*
- *Polyps* ■

NIDDK Provides Toll-Free Numbers for Clearinghouses

Out-of-state callers will be pleased to know that the National Institute of Diabetes and Digestive and Kidney Diseases has established toll-free lines for each of its three information clearinghouses:

- National Digestive Diseases Information Clearinghouse: 1–800–891–5389.
- National Diabetes Information Clearinghouse: 1–800–860–8747.
- National Kidney and Urologic Diseases Information Clearinghouse: 1–800–891–5390. ■

Panel Meeting, *continued from page 1*

NDDIC's interest in health disparities stems from a recent Department of Health and Human Services initiative to eliminate or reduce minority health disparities by the year 2010 in six areas: cancer screening and management, infant mortality, HIV/AIDS, heart disease, diabetes, and immunizations. The National Institutes of Health, of which the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is a part, took the initiative a step further, calling for all Institutes to develop a plan for addressing health disparities in their disease areas. NIDDK's plan is in development.

At the panel meeting, Dr. Trotman described how esophageal cancer, chronic hepatitis C, and colorectal cancer disproportionately affect African Americans, explaining risk factors, diagnosis, and treatment. For more information on the activities of AGA's Underrepresented Minorities Committee, contact Rokhsan Fallah at (301) 654–2055, extension 669. ■

What's New in CHID?

The Combined Health Information Database (CHID) is produced by health-related agencies of the Federal Government. This database provides the titles, abstracts, and availability of health information and health education resources. NDDIC maintains the digestive diseases section of the database, which includes information about books, pamphlets, videos, journal articles, and manuals on a variety of digestive disease topics. NDDIC continually adds new materials to CHID; following are brief examples of recent additions. To search CHID for materials on specific topics, go to *chid.nih.gov* on the Internet.

Directory of Plain Language Health Information

The reading level of patient education materials is often higher than that of the people who need the materials. This directory lists "plain language" patient education materials. An extensive introductory chapter describes how these materials are evaluated and offers specific information about the best strategies to use to create plain language materials. Each piece of health information in the directory is rated to help readers choose materials. The directory has three parts. Part I lists health subjects, part II lists organizations and their contact information, and part III provides an alphabetical list of all the organizations in part II.

Available from the Canadian Public Health Association, 400–1565 Carling Avenue, Ottawa, Ontario, Canada K1Z 8R1; (613) 725–3769. Price: $14.25, U.S. currency (plus shipping and handling). Also available free of charge at *www.pls.cpha.ca* on the Internet.

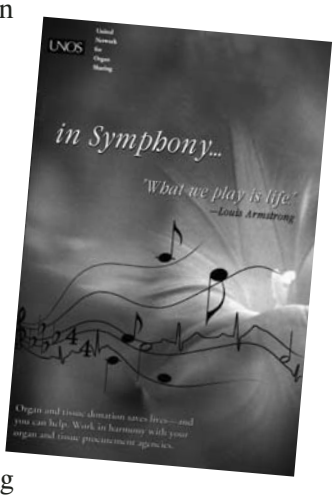
Food Labels: How To Use Them

This brochure offers information on food labels and how to use them to track calories and fat in the daily diet. It recommends that when people shop for groceries, they take the time to compare the labels on the different brands of food to see whether their favorites are the healthiest choices. The brochure largely consists of a copy of the Nutrition Facts label, with each part assigned a letter code. Also included is a chart that lists health claims and that notes which words can be used on the food label.

Available from Hope Publications, 350 East Michigan Avenue, Suite 301, Kalamazoo, MI 49007–3851; (616) 343–0770 (web site: *www.hithope.com*). Price: 59 cents each for 10 to 99 copies; 49 cents each for 100 to 299 copies.

In Symphony

This brochure reminds health care providers that the shortage of donor organs means that they must work with local organ procurement organizations to help make transplantation a viable option. Offering statistics about the waiting list for organ transplantation, *In Symphony* then reviews related issues. Who can be considered as a donor and which tissues and organs can be donated are discussed, as are the use of living donors, the success rates of organ transplantations, brain death criteria, and family reaction to organ donation. Also tackled are the administration of organ donation and transplantation in the United States, the allocation of organs, the way families are offered the option of organ donation, the cost considerations, and the health care professional's legal responsibility regarding organ and tissue donation.



Available from United Network for Organ Sharing (UNOS), 1100 Boulders Parkway, Suite 500, P.O. Box 13770, Richmond, VA 23225–8770; 1–888–894–6361 or (804) 330–8541. Price: 70 cents each; bulk copies available.

New in CHID, *continued on page 8*

Eye on the Intestine: New Capsule Endoscope Awaits FDA Approval for U.S. Testing

Examining the stomach and intestines may become much easier for gastroenterologists. A new wireless endoscope that takes images of the digestive tract was developed and recently tested by researchers from England and Israel. The device, in the form of a small capsule that the patient swallows, is awaiting approval by the U.S. Food and Drug Administration (FDA) for testing.

Test participants will have been referred for endoscopic exams of the small intestine, including exams to check for sources of bleeding. Some participants will receive the capsule and the rest will undergo conventional endoscopy, and researchers will compare the findings.

Unlike conventional endoscopes, says Paul Swain, M.D., a researcher from England, the capsule has no external wires or cables and the intestines do not have to be inflated with air. The capsule contains a miniature video camera, a battery, a tiny light, and a transmitter. The patient simply swallows the capsule and proceeds with his or her daily activities. According to Dr. Swain, the capsule "is propelled by peristalsis through the gastrointestinal tract and does not require a pushing force to propel it through the bowel." The capsule can record images for more than 5 hours.

Ten volunteers participated in the first study in England. None had trouble swallowing the capsule or discomfort as it traveled through their digestive tracts. The capsules sent images of the stomach, intestines, and colon to portable recorders that the volunteers wore on belts.

Dr. Swain said that the images from the capsule "are not yet quite as good as the best video-endoscopic images from conventional endoscopes." He added, however, that the capsule images obtained from the small intestine "are already superior to those obtained with the sonde-type long fiberoptic instruments."

Dr. Swain said that the capsule appears to give researchers complete views of more than 80 percent of the gastrointestinal tract, and he expects improvements as more studies are conducted. He added that the cost is competitive with conven-

NEW CAPSULE, *continued on page 7*

Vital Statistics

NDDIC, a service of the National Institute of Diabetes and Digestive and Kidney Diseases, answers inquiries about digestive diseases from the public and health professionals and produces and distributes educational materials on various digestive diseases, among other activities. Following are some statistics about NDDIC activities from April 1999 to April 2000.

- NDDIC responded to more than 20,000 inquiries from patients and health professionals.
- Patients and their family and friends continue to be the primary users of NDDIC services.
- NDDIC distributed more than 364,000 publications in response to inquiries.
- The most popular publications were *Irritable Bowel Syndrome, Diverticulosis and Diverticulitis, Chronic Hepatitis C: Current Disease Management,* and the three easy-to-read booklets about hepatitis A, B, and C.
- NDDIC exhibited at eight professional meetings and sent materials to a variety of health fairs throughout the Nation. ■

National Institutes of Health Launches *ClinicalTrials.gov*

A new National Institutes of Health (NIH) database gives the public easy access to information about research studies. The consumer-friendly database, *ClinicalTrials.gov,* has information on more than 4,000 Federal and private medical studies involving patients and others at more than 47,000 locations nationwide. The database may be reached at *ClinicalTrials.gov* or through the National Library of Medicine's web site at *www.nlm.nih.gov* on the Internet.

Clinical trials are medical research studies that seek to evaluate the safety and effectiveness of new drugs, medical procedures, or other means of treating, diagnosing, or preventing diseases. This type of research helps investigators learn how people respond to medications or other therapeutic approaches; such investigations may lead to new and improved treatments. Trials test which treatment works best for a particular disease or condition.

ClinicalTrials.gov provides patients, families, and the public with easy access to information about the location of clinical trials, their design and purpose, criteria for participation, and, in many cases, further information about the disease and treatment under study. Entries include links to individuals responsible for recruiting participants for each study.

ClinicalTrials.gov grew out of 1997 legislation that required the Department of Health and Human Services, through the NIH, to broaden the public's access to information about clinical trials on a wide range of diseases by establishing a registry for both federally and privately funded trials "on drugs for serious or life-threatening diseases and conditions" (Section 113, "Information Program on Clinical Trials for Serious or Life-Threatening Diseases," Food and Drug Administration Modernization Act of 1997, Public Law 105–115).

In the first phase of this project, the database's creators focused on studies that are being funded by NIH or conducted on the NIH campus. In the second phase, they will add information about non–NIH-sponsored trials from other Federal agencies and private industry.

ClinicalTrials.gov is a completely confidential web site. No registration or personal identification of any kind is required, and people who search the site will not be contacted by the sponsors of clinical trials or by anyone else. ■

HEPATITIS C STUDY, *continued from page 1*

(Pegasys, Hoffman LaRoche) and ribavirin for 20 weeks. Pegylated interferon is a new, long-acting form that people appear to tolerate better than standard interferon.

After the initial treatment, those whose blood continues to harbor the virus will be randomly divided into two groups. The control group will discontinue treatment, and the study group will continue treatment with pegylated interferon alone for 42 months. Patients in both groups will be evaluated every 3 months to determine whether the rate of cirrhosis and its complications declines. Patients will also receive liver biopsies at the start of the study and at the end of the second and fourth years.

In addition to studying the impact of long-term interferon treatment on liver disease, the study will also allow researchers to learn more about the long-term effects of interferon; the natural history of hepatitis C; and the effect of nutrition, obesity, smoking, and alcohol use on disease progression. Also, since the trial is part of NIDDK's strategic plan for addressing health disparities among minorities, minority recruitment will be emphasized. (The draft strategic plan is at *www.niddk.nih.gov/federal/strategicplan.htm* on the Internet.)

Patient recruitment began in July 2000. Participating clinical centers are

- Liver Disease Section, NIDDK (Bethesda, MD)
- Massachusetts General Hospital (Boston)
- Medical College of Virginia (Richmond)
- Saint Louis University (Missouri)
- University of California at Irvine
- University of Colorado Health Sciences Center at Denver
- University of Massachusetts (Amherst)
- University of Michigan (Ann Arbor)
- University of Southern California (Los Angeles)
- University of Texas Southwestern Medical Center (Dallas)

Additional information about the study, including eligibility and exclusion criteria, is available by contacting Study Coordinators Roxanne Lockhart at (617) 724–9456 or Amanda Ludwig at (617) 726–3630. ■

Quality of Sleep Affects IBS Symptoms in Women

According to researchers at the University of Washington in Seattle, a poor night's sleep for women with irritable bowel syndrome (IBS) can mean more than the usual gastrointestinal symptoms the following day.

For the study, 82 women with IBS and 35 women without IBS kept a record of their daily sleep habits and digestive symptoms for about 5 weeks (two menstrual cycles). They rated the severity of sleep disturbances such as trouble falling asleep, restless or disturbed sleep, early awakening, and insomnia, and the severity of IBS symptoms such as abdominal pain, bloating, constipation, diarrhea, and gas.

The results indicate that for women with IBS, a poor night's sleep leads to more gastrointestinal symptoms the next day. The findings remained the same when the researchers controlled for psychological distress and stress. Why the quality of sleep would affect digestive symptoms in women with IBS is unclear, but it could be related to a disturbance in the autonomic or central nervous systems that affects both sleep and gastrointestinal function.

The study was published in the May 2000 issue of *Digestive Diseases and Sciences.* Other researchers have found similar results in previous studies. ■

Gene Test for Hemochromatosis Could Save Lives With Wider, Earlier Use

In 1998, a team of medical researchers at the Saint Louis University School of Medicine provided valuable insight into the genetic mechanisms that contribute to hereditary hemochromatosis (HH), a common autosomal recessive disorder that results in increased iron absorption. (An autosomal recessive disorder occurs when the defective gene is passed on by both parents.) This knowledge helped lead to the development of a genetic test for screening that allows physicians to detect the disease early enough to prevent the deadly consequences of untreated HH. According to recent research, however, many physicians may not use or know about this screening tool.

HH can progress silently until toxic iron deposits in the liver and other organs cause cirrhosis, liver cancer, diabetes, heart failure, and, in some cases, death. With early detection, the simple act of regular blood-letting (called prophylactic phlebotomy) can prevent iron buildup.

The Missouri research team was supported in part by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The team was testing the theory that a mutation in a gene identified as *HFE* was responsible for HH.

To test the gene, researchers created a mouse model for the human disease. They identified the murine homologue, or mouse version, of the *HFE* gene and disrupted it in a number of mice. The gene-knockout mice (those with the disrupted gene) showed iron concentrations in the liver that were eight times higher than those of their normal littermates.

Before this study, scientists knew that 90 percent of patients with HH had the same mutation (C282Y) in the *HFE* gene. But they could not be sure whether the mutation was responsible for the defect in iron metabolism or whether it was just an innocent abnormality linked to an as-yet-unidentified gene that actually caused the problem. The mouse knockout model has helped confirm that the *HFE* mutation is the cause of HH and paved the way for the commercial development of a genetic test.

The new *HFE* mutation analysis test has not replaced the need for traditional diagnostic procedures, which include measuring the amounts of iron in the blood and the body, and liver biopsies are still needed to check for iron deposits and cirrhosis. But the DNA-based test is useful in screening family members of people with HH for the potential to develop the disease.

Unfortunately, indications are that the test is not being widely used for this purpose. As reported in the May 2000 issue of the *Southern Medical Journal,* a team of researchers recently surveyed physicians in Arkansas to determine how widely knowledge and use of the test had spread. Results indicated that only 21 percent of the physicians surveyed knew of the test, and only 10 percent knew it was available in Arkansas. Further, only 3 percent of those responding had actually given the test, and only one physician had used the test to screen the relatives of a patient with confirmed HH. ■

New Capsule, *continued from page 4*

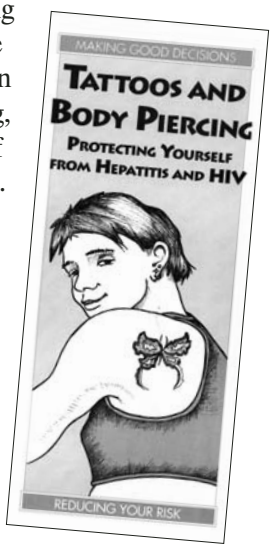
tional endoscopes and should be reasonably inexpensive if manufactured in large numbers.

Despite the success of the first studies, Dr. Swain found it unlikely that the capsule will replace endoscopy or colonoscopy altogether. "The capsule does not take biopsies," he said, "and it is hard to imagine that it could remove large polyps from the colon."

Upon FDA approval, Blair Lewis, M.D., of Mount Sinai Hospital in New York, will direct tests of the capsule in the United States. ■

NEW IN CHID, *continued from page 3*

Tattoos and Body Piercing: Protecting Yourself From Hepatitis and HIV



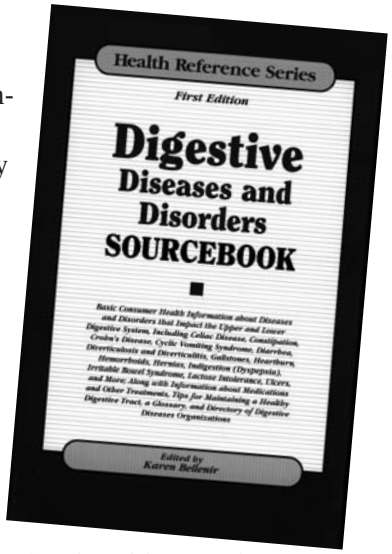
One in a series entitled "Making Good Decisions," this brochure offers young people information about tattoos and body piercing, focusing on reducing the risk of hepatitis and HIV transmission. The brochure recommends that young people recognize the risks of body piercing or tattooing, use only a professional tattooist or piercer, make sure tattoo inks are not shared or reused, and make sure the tattooist or piercer sterilizes all equipment and uses a new, disposable needle for each customer.

Available from Journeyworks Publishing, P.O. Box 8466, Santa Cruz, CA 95061; 1–800–775–1998 (web site: *www.journeyworks.com*). Price: $15 for a packet of 50; discounts available for larger orders.

CHID online

Digestive Diseases and Disorders Sourcebook

This sourcebook provides basic information for the lay audience about common disorders of the upper and lower digestive tract. Information about medications and recommendations for maintaining a healthy digestive tract are included. The book's 40 chapters are arranged in three major parts. The first section is about maintaining a healthy digestive tract, the second describes digestive diseases and functional disorders, and the third offers a glossary of terms, a subject index, and a directory of digestive diseases organizations—which includes web site and email addresses as available.



Available from Omnigraphics, Inc., 615 Griswold, Detroit, MI 48226; 1–800–234–1340. Price: $48 (plus shipping and handling). ■

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